



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807 and 812

[Docket No. FDA-2016-N-2518]

Medical Devices; Custom Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending its regulations on the definition of a custom device so as to include new enumerated statutory requirements for custom devices under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). This new provision, under FDASIA, amends the existing custom device exemption and introduces new concepts and procedures applicable to custom devices. This action is being taken to align the regulations with the FD&C Act.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Erica B. Payne, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5520, Silver Spring, MD 20993, 301-796-3999.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, section 617 of FDASIA (Pub. L. 112-144), amended the FD&C Act (21 U.S.C. 301 et seq.), to require changes in the implementation of the custom device exemption

under section 520(b) of the FD&C Act (21 U.S.C. 360j(b)) (Ref. 1). Under the revised provision, as under the original custom device exemption, a device that meets the qualification of a custom device is exempt from 510(k) and Premarket Approval (PMA) submissions under sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) (see also §§ 807.85 and 812.3(b) (21 CFR 807.85 and 812.3(b))). Because of the amendments to section 520(b) of the FD&C Act, the current regulatory definition for a custom device, set forth in §§ 807.85(a) and 812.3(b), is no longer consistent with the statute. This technical amendment will correct the regulations by revising the definition of a custom device to restate the statute.

Under existing regulations at § 807.85(a), a custom device is exempt from premarket notification under section 510(k) of the FD&C Act. In the Federal Register of August 23, 1977 (42 FR 42520 at 42523), FDA published a final rule establishing the form and manner for 510(k) premarket notifications, which identified a custom device as an exemption from the premarket approval requirement because a principal purpose for requiring 510(k) premarket notification is absent. The final rule explained that the exemption for manufacturers of custom devices is intended to apply only to those who are manufacturing a custom device to fit the needs of a particular patient, so the manufacturer will not be required to file a premarket notification for each particular device.

In the Federal Register of January 18, 1980 (45 FR 3732 at 3740), FDA published a final rule setting forth the rules and conditions under which investigations for medical devices involving human subjects may be exempt from certain requirements of the FD&C Act. The 1980 final rule provided clarification for the definition of “custom devices” under § 812.3(b) for Investigational Device Exemptions (IDE) unless used to determine safety and effectiveness for

commercial distribution. A device used to conduct a clinical trial cannot qualify as a custom device.

Section 520(b) of the FD&C Act, as amended by section 617 of FDASIA, changed some of the criteria to qualify for the custom device exemption, which is different from the criteria currently described in the regulations. The amendment to section 520(b) of the FD&C Act states that a device will qualify as a “custom device” by meeting new enumerated statutory requirements, including, among others, the following for each device: (1) is created or modified in order to comply with the order of an individual physician or dentist (or other specially qualified person); (2) necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515 of the FD&C Act; (3) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution; (4) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat; (5) either (a) is intended to meet the special needs of such physician or dentist in the course of the professional practice of such physician or dentist (or other specially qualified person as designated) in the course of their professional practice or (b) is intended for use by an individual patient named in the order of a physician or dentist (or other specially qualified person as designated); (6) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals, physician, or dentist; and (7) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices (21 U.S.C. 360j(b)).

The new provisions for the custom device exemption also include the following limitations: (1) the device is for the purpose of treating a “sufficiently rare condition, such that

conducting clinical investigations on such device would be impractical;” (2) the production of the device must be “limited to no more than five units per year of a particular device type”; and (3) a manufacturer is required to submit an annual report to FDA on the custom devices it supplied.

This technical amendment to the regulations for the custom device exemption will ensure clarity and consistency with the requirements of the FD&C Act. Some manufacturers might be unaware that certain medical devices that they distribute as custom devices do not meet the statutory definition as currently described in the regulations and are subject to premarket review. Also, FDA issued the final guidance entitled, “Custom Device Exemption” (Ref. 2) explaining the new statutory provisions for custom devices. The guidance provides definitions of certain terms used in connection with the custom device exemption and explains how FDA interprets the devices that may qualify for the custom device exemption under section 520(b) of the FD&C Act. The guidance also describes in further detail what information should be submitted in an annual report, and provides recommendations on how to submit an annual report for custom devices distributed under the exemption (Ref. 2). FDA finds good cause for issuing this amendment as a final rule without notice and comment because this amendment only corrects the implementing regulation to restate the statute (5 U.S.C. 553(b)(B)). “[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary.” Gray Panthers Advoc. Committee v. Sullivan, 936 F.2d 1284, 1291 (D.C. Cir. 1991). The amendments to §§ 807.85(a) and 812.3(b) merely incorporate applicable requirements of the FD&C Act, making notice-and-comment procedures unnecessary in this case. Therefore, publication of this document constitutes final action on this change under the Administrative Procedure Act (APA) (5 U.S.C. 553).

In addition, FDA finds good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date less than 30 days after publication as “provided by the agency for good cause found and published with the rule” (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments to §§ 807.85 and 812.3(b) do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for this correction to become effective on the date of publication of this action.

## II. References

The following references have been placed on display in the Division of Dockets Management (located at 5630 Fishers Lane, rm. 1061, Rockville, MD 20852), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. The Food and Drug Administration Safety and Innovation Act, available at <http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/ucm20027187.htm> or at <https://www.congress.gov/112/plaws/publ144/PLAW-112publ144.pdf>.
2. Custom Device Exemption; Guidance for Industry and Food and Drug Administration Staff; September 24, 2014, available at <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm415799.pdf>.

List of Subjects

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 807 and 812 are amended as follows:

PART 807--ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INTITIAL IMPORTERS OF DEVICES

1. The authority citation for part 807 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

2. Section 807.85 is amended by revising paragraph (a) introductory text to read as follows:

§ 807.85 Exemption from premarket notification.

(a) A custom device is exempt from premarket notification requirements of this subpart if the device is within the meaning of section 520(b) of the Federal Food, Drug, and Cosmetic Act.

\* \* \* \* \*

PART 812--INVESTIGATIONAL DEVICE EXEMPTIONS

3. The authority citation for part 812 continues to read as follows:

Authority 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b-263n.

4. Section 812.3 is amended by revising paragraph (b) to read as follows:

§ 812.3 Definitions.

\* \* \* \* \*

(b) A custom device means a device within the meaning of section 520(b) of the Federal Food, Drug, and Cosmetic Act.

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Dated: October 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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